

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION

Applicants : Balin et al.
Serial No. : 09/227,749
Filed : January 8, 1999
For : Treatment and Diagnosis
Of Alzheimer's Disease
Group Art Unit : 1200
Examiner : Eli Peselev

DECLARATION OF DR. STEVE FEINSTEIN

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

1. I, Dr. Steve Feinstein, make the following Declaration regarding the above application.
2. I have read the above patent application, cited references and outstanding office action in the above patent application.
3. There are several issues in regards to the Koskiniemi et al report and examples within the patent application of Balin et al. that I would like to address. First and foremost, in my expert opinion, the observations reported within the patent application, when confirmed, would represent a complete

- shift in the focus of therapy for patients with Alzheimer's disease, from barely treating the symptoms to aggressively attempting to prevent its onset.
4. There is no known cause of sporadic Alzheimer's disease and the body of work described in the patent application of Ballin et al. represents the first completely new research approach in many years.
 5. In terms of the specific issues relating to the rejection of the application, I would point out that the work of Koskiniemi et al. is a poor example of effective treatment for CNS infection by *Chlamydia pneumoniae*. The authors never proved that there was an active *Chlamydia pneumoniae* infection in the CNS in any of the meningitis patients described. This is in direct contrast to the large body of work provided in the Ballin application that proved the presence of *Chlamydia pneumoniae* in 17 of 19 patients who suffered from Alzheimer's disease.
 6. Secondly, Koskiniemi et al do not define the cell type infected and thus, do not teach sufficiently to use their observations as a model to treat other patients with *Chlamydia pneumoniae* infection related to chronic neurologic disease.
 7. Thirdly, we do not know whether the antibiotic treatment described resulted in suppression of said infection versus clearance of bacteria. Given these flaws, as well as the fact that as a clinician I would be making a therapeutic decision for chronic infections rather than an acute infection described by Koskiniemi et al, I would not be comfortable using it as a model for treating *Chlamydia pneumoniae* infections related to Alzheimer's disease. In fact, I

do not think Koskiniemi et al. even teaches effectively the appropriate treatment of Chlamydia pneumoniae associated meningitis.

The undersigned declares further that all statements made herein of his own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful, false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of any patent issuing therefrom.

Further Declarant sayeth not.

April 23, 2002

A handwritten signature in cursive script, appearing to read "St Felnstein", followed by a small flourish.

Steve Felnstein, M.D.